REMARKS

Reconsideration of this Application and entry of this Amendment is respectfully requested. By the amendments, Applicant does not acquiesce to the propriety of any of the Examiner's rejections and does not disclaim any subject matter to which Applicant is entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

No new matter has been added as a result of the present amendments.

In the claims

Claim 12 is currently amended to further clarify the claimed subject matter. Claims 1-6, 8-10, and 17-18 are hereby canceled. Claims 12-21 are pending in the application.

35 U.S.C. §112 Rejections

The Action rejects claims 1-10, 17, and 18 under 35 USC 112, first paragraph. Specifically, the Action asserts that the amendments made to claim 1 in response to the Office Action of September 18, 2009, ("with a hollow bore" and "wherein the administration of said liquid solution comprising botulinum toxin does not follow the administration of a first drug within said session") are not supported by the claims as originally filed or the specification. *See* Office Action at p3.

Respectfully, in accordance with MPEP 2163(I)(B), it is pointed out that "there is no *in haec verba* requirement, thus newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure." As previously explained, paragraph 44 is replete with U.S. Patents and Applications related to the botulinum toxin arts, and these are incorporated by reference into the instant disclosure. These references provide ample support for the assertion that hollow bore needle administration of botulinum toxin was well known in the art to those of ordinary skill.

Nevertheless, to expedite prosecution Applicant has cancelled the rejected claims, and requests that the Office withdraw the rejection.

35 U.S.C. §102 Rejections

The Action rejects 1-5, 8-10, and 12-21 under 35 USC § 102(e) as anticipated over U.S. Patent Publication No. 2006/0153876 ("Sanders") in light of American College of Foot and Ankle Surgeons: Hammertoes. Applicant respectfully traverses, however to expedite prosecution Applicant has amended the rejected claims to include the limitation of cancelled claim 6, which was not subject to the 35 U.S.C. §102 rejection. Thus, Applicant asks the Office to withdraw the rejection.

35 U.S.C. §103 Rejections

The Action rejects claims 1-6, 8-10, and 12-21 under 35 USC § 103(a) as unpatentable over Sanders in view of Gibbs *et al.* (BJM, 2002; 325:1-8).

To establish a *prima facie* case of obviousness under 35 U.S.C. §103, the Office must meet four conditions. First, the Office must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the Office must show that the prior art itself would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an Applicant's disclosure. Third, the prior art must teach or suggest all the claim limitations. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the Office must show a suggestion, teaching, or motivation to combine the prior art references ("the TSM test"). *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). As taught by *KSR Int'l Co. v. Teleflex, Inc.*, this fourth prong of the *prima facie* obviousness analysis must not be applied in a rigid or formulaic way such that it becomes inconsistent with the more flexible approach of *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966); 127 S. Ct. 1727 (2007). Nevertheless, it must still be applied, as the TSM test captures the important insight that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* at 1741 (citing *United States v. Adams*, 383 U.S. 39, 50-52 (1966)).

As amended, independent claim 12 recites a method for treating a wart in a patient in need thereof, the method comprising a step of administering by intradermal

injection or subdermal injection with a needle a therapeutically effective amount of a liquid solution comprising a botulinum toxin to a location of a skin disorder of the patient, wherein the administration of the botulinum toxin reduces at least one symptom of the skin disorder, thereby treating the skin disorder.

Sanders, which discusses the use of SNARE inhibitors including clostridial toxins, fails to recite "warts" entirely, and thus the Office cites Gibbs which supposedly discloses that "cutaneous warts can be painful on the soles of the feet and near the nails" and "suggest (*sic*) that local treatments be used to treat said warts." *See* Action at page 10. Applicant notes that Gibbs discloses nothing related to the SNARE inhibitors described in Sanders. To sum, Sanders teaches the use of SNARE inhibitors to treat a number of conditions not including warts, and Gibbs summarizes the effects upon warts of various treatments, none of which include SNARE inhibitors.

The initial requirement of the *prima facie* obviousness case requires the Office to show that the prior art suggested to those of ordinary skill in the art that they should carry out the claimed process. Here, one of ordinary skill would not find the instantly claimed invention suggested by the cited art, as the cited art fails to teach or suggest the use of botulinum toxin to treat a wart. As stated, Sanders teaches SNARE inhibitors and Gibbs teaches wart treatments, thus combined they cannot be said to teach the presently claimed method.

The next requirement of the *prima facie* obviousness case requires the Office to show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Here, the cited art does not do so, and in fact the Gibbs reference illustrates the uncertainty inherent to this field. For example, the reference states "[A] wide range of local treatments is available for treating warts . . .[N]o one treatment is strikingly effective and little is known about the absolute and relative efficacy of these treatments . . . [H]igh quality research on the efficacy of various local treatments for warts is lacking." Taken together, these statements demonstrate the cited art's failure to meet the second requirement of the *prima facie* case, as the statements show that one of ordinary skill would not, based upon the cited art, reasonably expect the claimed method to succeed. This is because the cited art both a) fails to suggest the claimed methods and b) demonstrates the informational vacuum

present in this field of study. Considering the absence of proven treatment methods, it is unlikely that one of skill would expect success if they were to combine the cited references.

The third element of the *prima facie* case obliges the Office to show that the prior art teaches or suggests all the claim limitations. Here, the Office suggests that the cited art does so, however merely identifying unrelated prior art references that describe claim elements cannot support a *prima facie* case, in the absence of a clear rational for combining the references. If no such teaching or suggestion were necessary, the Office could base §103 rejections upon the mere existence of claim elements in the prior art, and thus the final element of the *prima facie* case requires the Office to show a suggestion, teaching, or motivation to combine the prior art references. Here, no such teaching or suggestion exists. The Action states:

> It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Sanders with the teaching of Gibbs et al. to treat, via the reduction of at least one symptom (i.e. pain) of said wart with botulinum toxin because a symptom of warts include pain and inflammation and botulinum toxin is a known agent for treating pain. Moreover, botulinum toxin has unique properties that make them beneficial in medical applications.

Thus, the Office asserts that because warts can be painful, and botulinum toxins can be used to treat pain, that one of ordinary skill in the art would have been motivated to combine the cited references and employ botulinum toxin as a treatment for warts using the specific method steps presently claimed. By this line of reasoning, the use of botulinum toxin to treat any disorder that included pain among its symptoms would be obvious. Clearly, this cannot be the case, and the stated rationale is lacking. Better evidence as to what was inventive and non-obvious in this field is provided by Gibbs- of the fifty wart treatment trials cited in the 2002 paper, none utilized botulinum toxins. Despite this, by the Office's reasoning, the use of botulinum toxin to treat warts was, by the time of the present application's filing date in 2003, obvious.

The Office has not established a *prima facie* case of obviousness and the Applicant respectfully requests that the rejection be withdrawn.

CONCLUSION

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and a Notice of Allowance to that effect is respectfully requested. The Commissioner is hereby authorized to charge any additional fees which may be required for entry of this paper, or credit any overpayment, to Deposit Account No. 01-0885. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, the Examiner is kindly urged to call the undersigned at telephone number (714) 246-2842.

Respectfully submitted,

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